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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,233	12/01/2003	Irene Quenville	P03346	2124
23702	7590	11/03/2005	EXAMINER	
Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			DELCOTTO, GREGORY R	
			ART UNIT	PAPER NUMBER

1751

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,233

Applicant(s)

QUENVILLE ET AL.

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/24/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-17 are pending. Applicant's arguments and amendments filed 8/10/05 have been entered.

Applicant's election of Group I in the reply filed on 8/10/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/10/05.

Objections/Rejections Withdrawn

The following objections/rejections as set forth in the Office action mailed 3/10/05 have been withdrawn:

The objection to claims 1-7 due to minor informalities has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 2, Applicant has added different tradenames than originally presented in the claims which do not find support in the specification, as originally filed. Additionally, Applicant has not provided any statement in the response indicating what portion of the specification provides basis for the new surfactant names or how these names correspond to the originally filed tradenames. Thus, this is deemed new matter.

Claim 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to instant claim 2, this claim recites a Markush group of tradenames. Note that, if the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph. See MPEP 2173.05(u).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharian et al (US 6,228,323).

Asgharian et al teach a two-compartment bottle assembly useful in preparing multi-purpose compositions containing an Al-trypsin and disinfectant. These compositions are useful for cleaning and disinfecting contact lenses. See Abstract. The bottle may be made out of materials such as molded polyethylene, polyethyleneterephthalate (PET), etc. See column 5, lines 1-5. The disinfecting compositions generally contain one or more antimicrobial agents, a buffer, tonicity agents, a chelating agent, and surfactants (i.e. block copolymers). See column 11, lines 50-69. Specifically, Asgharian et al contain cleaning compositions containing 0.001% Polyquaternium 1, 0.6% boric acid, 0.1% sodium chloride, 0.05% Tetronic 1304, 0.05 disodium edetate, water, etc. See column 14, lines 25-45.

Asgharian et al do not teach, with sufficient specificity, an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition

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containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, for formulate an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of Asgharian et al suggest an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323).

'578 teaches an aqueous composition for cleaning and wetting a contact lens containing a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent, and wetting agent. See Abstract. The cleaning compositions also include buffering agents such as sodium carbonate. Also, the compositions may contain antimicrobial agents in amounts from 0.00001 to about 5% by weight. See para. 23-26. The compositions may also contain a sequestering agent such as EDTA.

Groemminger does not teach the use of a polyethyleneterephalate containing or an article of manufacture comprising a container formed from polyethyleneterephalate and a composition containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

Asgharian et al are relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to package the compositions taught by Groemminger in a polyethyleneterephalate container, at the time the invention was made, because Asgharian et al teaches the use of a polyethyleneterephalate container to package similar contact lens cleaning/disinfecting compositions.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, for formulate an article of manufacture comprising a container formed from polyethyleneterephalate and a composition containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of Groemminger in combination with Asgharian et al suggest an article of manufacture comprising a container formed from polyethyleneterephalate and a composition containing surfactants, antimicrobial agents, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharian et al (US 6,228,323) or Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323) as applied to the rejected claims above, and further in view of Winterton et al (US 5,209,865).

Asgharian et al and Groemminger are relied upon as set forth above. However, neither reference teaches the specific surfactant in addition to the other requisite components of the composition as recited by the instant claims.

Winterton et al teach a conditioning solution for contact lenses which comprises a polyoxyethylene-polyoxypropylene substituted ethylenediamine nonionic surfactant. See column 2, lines 1-11. Suitable surfactants include those under the trade name Tetronic and include Tetronic 1101, 1102, 1301, 1302, etc. which are synonymous with poloxamine 1101, 1102, 1301, 1501, etc. See column 3, lines 27-47.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a surfactant such as poloxamine 1101 or 1102 in the cleaning compositions taught by Asgharian et al or Groemminger, with a reasonable expectation of success, because Winterton et al teach the use of poloxamine 1101 or 1103 (e.g., Tetronic 1101 or 1301) in a similar contact lens cleaning composition and further, Asgharian et al or Groemminger teach the use of poloxamine (e.g., Tetronic) surfactants in general.

Response to Arguments

With respect to the prior art rejections, Applicant states that the specification indicates that PET containers have the unexpectedly positive result of promoting long-

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term stability of the composition and that the benefit of selecting a PET container over a PE container is well established in the Examples. In response, note that, the Examiner asserts that the comparative data presented in the specification is not sufficient to show the unexpected and superior properties of the claimed invention and overcome any prima facie case of obviousness. First, in Tables 2 and 3 which shows storage stability of PHMB and Alexidine, respectively, the PET container performs nearly the same as the HDPE container and there are large portions of data missing as indicated by "ND" which does not constitute any persuasive evidence. In Table 4, in the 6 month column, data is missing for one trial run and in Table 5, data is completely missing for all of the 8 month results for PET. It is not clear to the Examiner why the data is left out of these tables and the Examiner asserts that an accurate determination as to whether the data shows unexpected and superior results cannot be made based on the incompleteness of the data.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

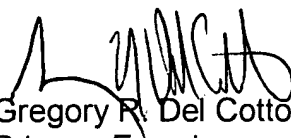
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gregory R. Del Cotto
Primary Examiner
Art Unit 1751

GRD
October 30, 2005